



Specification

1.00681.0000 Succinic acid cryst., EMPROVE® ESSENTIAL ChP,NF,JPE,ACS

Specification		
Assay (alkalimetric)	99.0 - 100.5	%
Assay (HPLC)	99.0 - 100.5	%
Identity (IR)	passes test	
Identity (HPLC)	passes test	
Identity (wet chemistry)	passes test	
In water insoluble matter	≤ 0.01	%
Melting range (lower value)	≥ 185.0	°C
Melting range (upper value)	≤ 190.0	°C
Melting point	185.0 - 190.0	°C
Chloride (Cl)	≤ 0.001	%
Phosphate (PO ₄)	≤ 0.001	%
Sulfate (SO ₄)	≤ 0.003	%
Heavy metals (as Pb)	≤ 0.0020	%
Heavy metals (as Pb) (ACS)	≤ 5	ppm
Nitrogen compounds (as N)	≤ 0.001	%
Fe (Iron)	≤ 5	ppm
As (Arsenic)	≤ 0.00015	%
Substances reducing permanganate	conforms	
Residual solvents (ICH Q3C)	excluded by production process	
Sulfated ash (600 °C)	≤ 0.02	%

Elemental impurity specifications have been set considering ICH Q3D (Guideline for Elemental Impurities). Class 1-3 elements are not likely to be present above the ICH Q3D option 1 limit, unless specified and indicated (*).

Corresponds to ChP, NF, JPE, ACS

The original manufacturer name and address will be disclosed subsequent to signing a confidentiality agreement.

Julian Hofmann

Responsible laboratory manager quality control

This document has been produced electronically and is valid without a signature.